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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,569	11/21/2003	Christina Khoo	7097-00	3558

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,569

Applicant(s)

KHOO ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 recite the phrases "a disease" and "a main component". However, the claim is indefinite because, it is unclear what disease (s) is characterized as having GI tract inflammation as a main component and what constitutes a main component. These phrases are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 10 recites the phrase "component". However, the claim is indefinite because, it is unclear what constitutes a component. More specifically, the chemical structure or name and/or physical characteristics of said component is not known.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Garleb et al. (US 5,444,054).

In claim 1, applicant claims "A method for reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract of a companion pet which comprises orally administering to the said pet a *Desulfovibrio* and/or *Helicobacter* spp. reducing quantity of a fiber selected from the group consisting of an oligosaccharide, a galactan, a beta glucan and a mixture thereof." Garleb et al. disclose applicant's method of treating inflammatory condition of the GI tract (including ulcerative colitis and inflammation of the colon) which comprises orally administering to a mammal (which can be a pet) a quantity of a fiber which is an oligosaccharide (a fructooligosaccharide or a xylooligosaccharide) (see claim 7; see col. 21, lines 14 to col. 22, line 62, and abstract). It should be noted that since Garleb et al. treat the same disease or condition (GI tract inflammation) by administering to a pet (e.g. a mammal), the same compound or active ingredient as applicant's (i.e., an oligosaccharide, fructooligosaccharide or xylooligosaccharide), then Garleb et al.'s method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. which inherently colonize the gastrointestinal tract (GI tract). Claims 2-5 which are drawn to a method of treating specific pets, specific pets with disease in which GI tract inflammation is the main component, and administering specific fibers including (fructooligosaccharide or xylooligosaccharide) to pets, are also anticipated by Garleb et al., since Garleb et al. treat the same pets (mammals) which have the same condition or disease (GI tract inflammation) with the same fiber (fructooligosaccharide or xylooligosaccharide) (see claim 7; see col. 21, lines 14 to col. 22, line 62, and abstract). It should be noted that since Garleb et al. treat the same disease or condition (GI tract inflammation) by administering to a pet (e.g. a mammal), the same compound or active ingredient as applicant's (i.e., an oligosaccharide,

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fructooligosaccharide or xylooligosaccharide), then Garleb et al.'s method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. which inherently colonize the gastrointestinal tract (GI tract).

In claim 7, applicant claims "A method for treating GI tract inflammation in a companion pet having an elevated level of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract comprising orally administering a *Desulfovibrio* and/or *Helicobacter* spp. reducing effective amount of a fiber." Garleb et al. disclose applicant's method for treating GI tract inflammation (including ulcerative colitis and inflammation of the colon) in a pet (mammal) which comprises orally administering to a mammal a quantity of a fiber which is an oligosaccharide (a fructooligosaccharide or a xylooligosaccharide) (see claim 7; see col. 21, lines 14 to col. 22, line 62, and abstract). It should be noted that since Garleb et al. treat the same disease or condition (GI tract inflammation) by administering to a pet (e.g. a mammal), the same compound or active ingredient as applicant's (i.e., an oligosaccharide, fructooligosaccharide or xylooligosaccharide), then Garleb et al.'s method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. which inherently colonize the gastrointestinal tract (GI tract).

In claim 9, applicant claims "A method for treating GI tract inflammation in a companion pet having an elevated level of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract comprising orally administering a *Desulfovibrio* reducing effective amount of a component which reduces the quantity of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract. Garleb et al. disclose applicant's method for treating GI tract inflammation (including ulcerative colitis and inflammation of the colon) in a companion mammal (which can be a pet) which comprises orally administering to a mammal a quantity of a fiber which is an oligosaccharide (a

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fructooligosaccharide or a xylooligosaccharide) (see claim 7; see col. 21, lines 14 to col. 22, line 62, and abstract). It should be noted that since Garleb et al. treat the same disease or condition (GI tract inflammation) by administering to a pet (e.g. a mammal), the same compound or active ingredient as applicant's (i.e., an oligosaccharide, fructooligosaccharide or xylooligosaccharide), then Garleb et al.'s method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. which inherently colonize the gastrointestinal tract (GI tract).

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Fujimori (US 5,294,458).

In claim 10, applicant claims "A method for reducing an odor selected from the group consisting of intestinal gas odor, stool odor and any mixture thereof in a companion pet having an elevated level of *Desulfovibrio* and/or *Helicobacter* spp. which comprises orally administering a *Desulfovibrio* and/or *Helicobacter* spp. reducing effective amount of a component which reduces the quantity of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract. Fujimori discloses applicant's method of reducing stool odor (feces odor) in a pet (an animal) which comprises orally administering an effective amount of a component (lactosucrose) in a pet food (see claim 3 and embodiment 2, col. 6, line 12 to col. 8, line 34). Fujimori discloses that his composition keeps the intestines of the pets (such as dogs and cats) in order, and greatly decrease unpleasant odors of feces and urine discharged by the pets (col. 8, lines 19-32). It should be noted that since Fujimori treats the same disease or condition (reducing odor) by administering to a pet, the same component which is also effective in the GI tract (intestines of GI tract), then Fujimori's method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. which inherently colonize the gastrointestinal tract (GI tract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hara (Phytochemicals and Phytopharmaceuticals (2000), 214-221. Editor (s): Shahidi, Fereidoon; Ho, Chi-Tang) in view of Garleb et al. (US 5,444,054).

In claim 1, applicant claims "A method for reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract of a companion pet which comprises orally administering to the said pet a *Desulfovibrio* and/or *Helicobacter* spp. reducing quantity of a fiber selected from the group consisting of an oligosaccharide, a galactan, a beta glucan and a mixture thereof." In claim 6, applicant claims "The method in accordance with claim 1 wherein a polyphenol is also present."

Garleb et al. disclose a method of treating inflammatory condition of the GI tract (including ulcerative colitis⁴) which comprises orally administering to a mammal (which can be a pet) a quantity of a fiber which is an oligosaccharide (a fructooligosaccharide or a xylooligosaccharide) (see claim 7; see col. 21, lines 14 to col. 22, line 62, and abstract). It should be noted that since Garleb et al. treat the same disease or condition (GI tract inflammation) by administering to a pet (e.g. a mammal), the same composition which contains the same ingredient as applicant's (i.e., an oligosaccharide, fructooligosaccharide or

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xylooligosaccharide), then Garleb et al.'s method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. which inherently colonize the gastrointestinal tract (GI tract).

Hara discloses a method for reducing the quantity of *Helicobacter* spp. (*Helicobacter pylori*) in the GI tract (stomach and intestines) of a patient which comprises orally administering to the said patient a *Helicobacter* spp. (*Helicobacter pylori*) reducing quantity of tea polyphenols (see abstract). In addition, Hara discloses that polyphenols have antibacterial effects on pathogenic bacteria in the stomach and alters intestinal microflora (see abstract). In addition, it is known that *Helicobacter pylori* (which inherently colonize the GI tract) causes inflammatory conditions of the GI tract.

The difference between applicant's claimed method and the method disclosed by Garleb et al. is that applicant also uses a polyphenol. However, Hara discloses that polyphenols have antibacterial effects on pathogenic bacteria in the stomach and alters the intestinal microflora. This suggests that polyphenols can be combined with a fiber (fructooligosaccharide or xylooligosaccharide) disclosed by Garleb et al. to treat inflammatory disease or condition of GI tract (stomach and intestine) caused by *Helicobacter* spp. (*Helicobacter pylori*).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Garleb et al. to treat inflammatory disease or condition of GI tract (stomach and intestine) with a composition comprising a combination of a fiber disclosed by Garleb et al. and a polyphenol disclosed by Hara, since the combination of compounds that are used to treat the same diseases or conditions is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to

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form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Garleb et al. and Hara, to use the method of Garleb et al. to treat inflammatory disease or condition of GI tract (stomach and intestine) with a composition comprising a combination of a fiber disclosed by Garleb et al. and a polyphenol disclosed by Hara, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Garleb et al. and Hara, to treat inflammatory disease or condition of GI tract (stomach and intestine), based on type and/or severity of the disease or condition.

In claim 7, applicant claims "A method for treating GI tract inflammation in a companion pet having an elevated level of *Desulfovibrio* and/or *Helicobacter* spp. in the GI tract comprising orally administering a *Desulfovibrio* and/or *Helicobacter* spp. reducing effective amount of a fiber." In claim 8, applicant claims "The method in accordance with claim 7 wherein a polyphenol is also present."

Garleb et al. disclose a method for treating GI tract inflammation (including the colon) in a pet (mammal) which comprises orally administering to a mammal a quantity of a fiber which is an oligosaccharide (a fructooligosaccharide or a xylooligosaccharide) (see claim 7; see col. 21, lines 14 to col. 22, line 62, and abstract). It should be noted that since Garleb et al. treat the same disease or condition (GI tract inflammation) by administering to a pet (e.g. a mammal), the same composition which contains the same ingredient as applicant's (i.e., an oligosaccharide, fructooligosaccharide or xylooligosaccharide), then Garleb et al.'s method should also occur via the same mechanism of reducing the quantity of *Desulfovibrio* and/or *Helicobacter* spp. (in the GI tract).

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Hara discloses a method for reducing the quantity of *Helicobacter* spp. (*Helicobacter pylori*) in the GI tract (stomach and intestines) of a patient which comprises orally administering to the said patient a *Helicobacter* spp. (*Helicobacter pylori*) reducing quantity of tea polyphenols (see abstract). In addition, Hara discloses that polyphenols have antibacterial effects on pathogenic bacteria in the stomach and on the intestinal microflora (see abstract).

The difference between applicant's claimed method and the method disclosed by Garleb et al. is that applicant also uses a polyphenol. However, Hara discloses that polyphenols have antibacterial effects on pathogenic bacteria in the stomach and on the intestinal microflora. This suggests that polyphenols can be combined with a fiber (fructooligosaccharide or xylooligosaccharide) disclosed by Garleb et al. to treat inflammatory disease or condition of GI tract (stomach and intestine).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Garleb et al. to treat inflammatory disease or condition of GI tract (stomach and intestine) with a composition comprising a combination of a fiber disclosed by Garleb et al. and a polyphenol disclosed by Hara, since the combination of compounds that are used to treat the same diseases or conditions is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Garleb et al. and Hara, to use the method of Garleb et al. to treat inflammatory disease or condition of GI tract (stomach and intestine) with a composition comprising a combination of a fiber disclosed by Garleb et al. and a polyphenol disclosed by Hara, because a skilled artisan would reasonably be


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expected to prepare a composition comprising a combination of the compounds taught by Garleb et al. and Hara, to treat inflammatory disease or condition of GI tract (stomach and intestine), based on type and/or severity of the disease or condition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.


JAMES O. WILSON
SUPERVISOR/EXAMINER
TECHNOLOGY CENTER

MCH

August 16, 2004.